STUDY SET UP Flow chart

Sponsor signed copies sent to Medical Director for signing. relevant copies sent to sponsor and Team.

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BHT details added and returned to sponsor for signing. Signed copies sent back to Facilitator.

**YES**

**YES**

Is there a contract?

Contract/costings reviewed by lead Nurse & facilitator and approved.

Radiology services required?

**NO**

**NO**

**NO**

Full document pack requested and accepted by Facilitator.

70 DAY TARGET BEGINS

Trust added as site (if not already done so).

Appendix B – prepared by Lead Nurse or delegated representative and PI - must be signed off by appropriate Consultant Medical Physicist. This can take time to process so needs to be completed ASAP. Sent to Facilitator.

Trust accepted as site – copy of protocol/statement of activities/costings only sent to Team & Facilitator

**YES**

Appendix A is completed by pharmacy and sent to Facilitator.

Feasibility held to ascertain the capacity & capability to deliver study. If agreed form is signed off.

by

Pharmacy services required?

Feasibility form completed by Lead Nurse or delegated representative. Copy sent to R&I Administrator with list of delegates/dates to arrange teleconference. Invites sent out.

70 DAYs from SITE SELECTED to 1ST patient consented – including SIV & GREEN LIGHT from Sponsor

30 Days from CAPACITY and CAPABILTY to 1ST patient consented

40 Days from SITE SELECTED (full set of docs.received) to CONFIRMATION of CAPACITY and CAPABILTY